# Health & Environmental Horizons, Ltd.

2851 South Haven Road Annapolis, MD 21401 410-974-6112/301-261-8491

August 28, 2008

Adam Heyward Regulatory Management Branch 2 (PM34) Antimicrobials Division (7510P) Office of Pesticide Programs Environmental Protection Agency 1200 Pennsylvania Ave., NW Washington, DC 20460

SUBJECT:

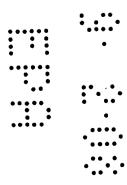
Response to EPA Approval of Conditional Registration of ChitoSante'

MUP, dated 5/20/08, EPA Registration 75100-2

#### Dear Adam;

On behalf of VA&G Bioscience, Inc., Health & Environmental Horizons, Ltd. (their US Agent), we are submitting a revised copy of the MUP Master Label (dated 8/28/08) and a primary eye irritation study. These documents satisfy the conditions outlined in EPA's May 20, 2008 Conditional Registration approval.

The results of the Primary Eye Irritation study demonstrate that the existing Signal Word, CAUTION, is unchanged and the Precautionary labeling is also consistent with existing language for a mild-moderate eye irritant. This is the same as for EPA Registration Number 81446-1, ChitoSante' (a 6% a.i. product). In accordance with previous decisions by EPA regarding ChitoSante's use on clothing we are requesting that the word "clothing" be removed from the Precautionary Statements for EPA Registration Number 75100-2 as well (see EPA approval letter for EPA Registration No. 81446-1, February 13, 2007). Also, we believe the additional requested precautionary statements in your letter, para 2. b., viz. "...and before eating, drinking, chewing gum, using tobacco or using the toilet" are redundant and possibly exclusive of other "potential" sources of contact. We believe that the existing statement "Wash thoroughly with soap and water after handling" is sufficient, succinct, and complete and no additional recommended statements are necessary or useful. If you concur we will revise our label accordingly.



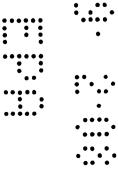
Finally, we believe that with this submission VA&G Bioscience has fully complied with the conditions of your May 20, 2008 letter and we hereby request a full unconditional registration for ChitoSante' MUP. Once again, we wish to thank you and your staff for your assistance.

Sincerely,

President 4

Atch.: (1)Copy of revised Master Label for ChitoSante' MUP dated 8/28/08

(2) Transmittal document for Eye Study



# VOLUME 1 OF 2 OF SUBMISSION TRANSMITTAL DOCUMENT

#### NAME AND ADDRESS OF APPLICANT/SUBMITTER;

Ya Chung Wei, Ph. D Chief Executive Officer No. 29 Chang-an Street, Bade City Taoyuan, Taiwan 33465, R.O.C.

#### U.S. AGENT/REPRESENTATIVE:

R. Bruce Jaeger President Health & Environmental Horizons, Ltd. 2851 South Haven Rd. Annapolis, MD 21401

### **REGULATORY ACTION:**

Submission of Primary Eye Irritation Study for ChitoSante' MUP, EPA Reg. No. 75100-2.

# **TRANSMITTAL DATE:**

August 28, 2008

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE Number
	1 of 2	Transmittal Document	-
475266 <u>0</u> 1	2 of 2	Document Number 1: Primary Eye Irritation Study in Rabbits	158.340 870.2400

COMPANY OFFICIAL:

R. Bruce Jaeger

Signature:

**COMPANY NAME:** 

VA & G Bioscience, Inc.

**COMPANY CONTACT:** 

R. Bruce Jaeger

AGENT/REPRESENTATIVE:

R. Bruce Jaeger

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